

REMARKS

This Amendment and Response responds to the Office Action dated November 3, 2005. Claim 37 is amended to place this claim in better form for appeal. No claims are cancelled or added. As a result, claims 1-47 are pending in this patent application.

1. **Real Party In Interest**

The real party in interest of the above-captioned patent application is the Assignee, Cardiac Pacemakers, Inc.

2. **Related Appeals and Interferences**

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in an appeal of this matter.

3. **Status of the Claims**

Claims 1-47 are currently pending in this patent application. A Final Office Action was mailed on November 3, 2005. Claims 20-27 have been allowed. Claims 1-19 and 28-47 stand finally rejected, and their rejection is the subject of the appeal of this matter.

4. **Status of Amendments**

Claim 37 has been amended after the Final Office Action that was mailed on November 3, 2005, to make it consistent with the existing claim 1 and, therefore, to put claim 37 in better condition for appeal.

5. **Summary of Claimed Subject Matter**

Independent apparatus claim 1 relates to an implantable far-field telemetry module (*see, e.g., Application, Fig. 2 at 130*) including at least one data interface connector (*Fig. 7 at 433C*) adapted to connect the telemetry module 130 to an implantable medical device (*Figs. 2 & 7 at 105*). This permits wired communication of data from the implantable medical device 105 to the telemetry module 130. (*See Application at page 18, lines 28-30.*) The telemetry module 130, in

turn, provides wireless communication of the data to an external device. (*See* Application at page 9, line 22 through page 10, line 1.) The interface connector 433C is a user-attachable connector or a detachable connector. (*See, e.g.*, Application at page 10, lines 14-26.)

Independent method claim 28 relates to connecting a user-attachable or detachable implantable far-field telemetry module 130 to an implantable medical device 105 to provide “wired” transmission of data from the implantable medical device to the telemetry module. (*See* Application at page 18, lines 28-30.) The telemetry module 130, in turn, is used to provide far-field wireless telemetry of the data from the implantable medical device. (*See* Application at page 9, line 22 through page 10, line 1.)

Independent method claim 37 relates to connecting a user-attachable or detachable implantable far-field telemetry module 130 to an implantable medical device. Far-field telemetry is provided for the implantable medical device 105 using the telemetry module 130. The far-field telemetry includes receiving, via “wired” communication using an electrical conductor, a first data stream from the implantable medical device 130. (*See* Application at page 18, lines 28-30.) A first radio-frequency RF carrier suitable for far-field data transmission from within a body is generated using the telemetry module 105. (*See* Application at page 9, line 22 through page 10, line 1.) The first RF carrier is modulated to be representative of the first data stream. (*See id.*) The modulated first RF carrier is wirelessly transmitted. (*See id.*)

This summary is provided for the convenience of the Board of Appeals and Patent Interferences. It is not to be used to limit the scope of the claims.

6. Grounds for Rejection to Be Reviewed on Appeal

- 1) Was a *prima facie* case of anticipation under 35 U.S.C. § 102(e) properly made with respect to claims 37-39, 42, and 44-47 using Thompson et al. (U.S. Patent No. 6,675,049)?
- 2) Was a *prima facie* case of obviousness under 35 U.S.C. § 103(a) properly made with respect to claims 1-19 and 28-36 using Thompson et al. (U.S. Patent No. 6,675,049) in view of Goedeke et al. (U.S. Patent No. 6,167,312)?

7. Argument

A) *The Applicable Law*

Anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *See Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, “[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). “The *identical invention* must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131 (emphasis added). In interpreting the claims it is widely recognized that a patentee is free to be his own lexicographer. *See, e.g., Autogiro Co. of America v. United States*, 384 F.2d 391, 397 (Ct. Cl. 1967). However, unless a special definition is clearly stated in the patent specification or prosecution history, claim terms are to be given their ordinary and customary meaning in the field of the invention. *See Vitronics*, 90 F.3d at 1582, 39 U.S.P.Q.2d at 1576.

The Examiner also has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d (BNA) 1596, 1598 (Fed. Cir. 1988). In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* The M.P.E.P. contains explicit direction to the Examiner that agrees with the *In re Fine* court:

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed

combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d (BNA) 1443 (Fed. Cir. 1992). However, while it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). The requirement of a suggestion or motivation to combine references in a *prima facie* case of obviousness is emphasized in the Federal Circuit opinion, *In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002), which notes that the motivation must be supported by evidence in the record.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). References must be considered in their entirety, including parts that teach away from the claims. See MPEP § 2141.02. The fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); *M.P.E.P.* § 2143.01.

B) The References

Thompson: describes an implantable medical device (IMD) with a user-attachable or detachable lead. A distal portion of the lead includes an RF communications circuit that apparently communicates wirelessly with both the IMD and an external device.

Goedeke: describes an external programmer with a removable antenna that can be coupled to the external programmer either wirelessly or with a cord. (See Goedeke at col. 7, lines 49-67.)

C. Discussion of the Rejections

C.1 The Rejection of claims 37-39, 42, and 44-47 using Thompson et al.

As an initial note, Appellant does not admit that Thompson et al. is prior art. Appellant reserves the right to swear behind Thompson et al. at a later date. Moreover, because Thompson et al. fails to disclose the identical invention as claimed, Appellant respectfully traverses this rejection as discussed below.

Appellant has amended claim 37 to recite receiving, via wired communication using an electrical conductor, a first data stream from the implantable medical device. By contrast, the Thompson et al. device apparently uses wireless communication between an implantable medical device (using transmitter receiver circuit 380 and antenna 260 of FIG. 3) and the passive transponder 262, which is mounted on the intravascular lead that is attached to the implantable medical device. Accordingly, Thompson et al. fails to disclose all elements presently recited or incorporated in the claims 37-39, 42, and 44-47. Therefore, Applicant respectfully requests reversal of this basis of rejection of these claims.

C.2 The Rejection of claims 1-19 and 28-36 under 35 U.S.C. § 103(a) using Thompson et al. in view of Goedeke et al.

Appellant respectfully submits that there is no *prima facie* case of obviousness of claims 1-47 because Thompson et al. and/or Goedeke fail to disclose, teach, or suggest wired data communication between the implantable medical device and a user-attachable or detachable far-field telemetry module, which, in turn, provides far-field wireless communication with another location.

In asserting this § 103 rejection, the Final Office Action states:

As to claims 1 and 28 applicants have added the term “wired” to define over the Thompson wireless data transmission to the external to the IMD telemetry module, however it is widely accepted in the art that wired and wireless (as well as other transmission modalities as optical, etc.) are known functional equivalents and therefore the subject of design considerations lacking in patentable moment. For example, Goedeke et al. teach that wired and wireless connections are interchangeable in the implantable device telemetry art, col. 7 at lines 27-67. As

such it would have been obvious to those having ordinary skill in the art at the time of the invention to have utilized a wired communication path in the Thompson et al. device instead of the disclosed wireless path as a mere substitution of known functionally equivalent data transmission options.

(Final Office Action at 3.) Applicant respectfully disagrees.

First, Goedeke actually only describes the alleged interchangeability of wired and wireless communication outside the human body, that is, in the context of a removable antenna for an external programmer—not with respect to components that are actually chronically implanted in the human body. (See Goedeke at column 7, lines 54-67.) In fact, chronic implantation within the human body necessarily renders wired and wireless communications non-interchangeable, since these different communication modalities typically have vastly different power consumption requirements and, therefore, are not at all equivalent in the context of a long-life battery-powered implantable device.

Second, in asserting that the claimed invention is obvious on the grounds that wired and wireless communications modalities are functionally equivalent, the Final Office Action improperly collapses the obviousness analysis away from considering the invention as a whole. Instead, the Final Office Action has deconstructed the claim into constituent components in order to assert obviousness. This is clearly improper, since the test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). Appellant respectfully submits that when the claimed invention is considered as a whole—including the problem to be solved by the combination of elements—the claimed invention is clearly non-obvious.

What is an example of a problem to be solved by the present claimed invention? Existing implantable medical devices with telemetry (including the device shown in Thompson et al.) typically are manufactured with the same type of telemetry circuit for all such devices of a particular model type. However, the present inventors have recognized that a particular patient's telemetry needs may differ from another patient's telemetry needs—even though both such patients would otherwise be suitable candidates for the same model of implantable medical device. (See, e.g., Application at page 4, lines 5-8.) As an illustrative example, a first patient

may live in a first country, which by its laws requires communication at a first frequency, and a second patient may live in a different second country, which by its laws requires communication at a different second frequency. The present user-attachable and detachable telemetry module would allow a clinician or other user to use a particular far-field telemetry module for a particular patient that is tuned or otherwise particularly adapted to best serve that patient's telemetry needs. By contrast, with the Thompson et al. arrangement, if a clinician or other user were to swap different passive transponders for use with a particular patient, such different passive transponders would still have to communicate with the same fixed RF transmitter receiver circuit 338 within the implantable medical device of Thompson et al. Therefore, the implantable medical device of Thompson et al. would not have been in any way altered to provide a customized RF communications circuit 338. By contrast, the present claimed invention allows the user to mix-and-match far-field telemetry modules and implantable medical device models, thereby allowing greater flexibility in meeting a particular patient's needs.

Moreover, where geographic or political regions impose different telemetry requirements, as discussed above, allowing such a mix-and-match between implantable medical device models and user-detachable and attachable telemetry units advantageously makes global distribution of product an easier task for the manufacturer.

Furthermore, if one of the implantable medical device and the user-detachable and attachable remote far-field telemetry module were to fail, it could be replaced without replacing the other, resulting in cost-savings to the patient.

In sum, because all claimed elements are not shown in Thompson et al. and Goedeke, and because wired and wireless communications cannot be viewed as functional equivalents in the implantable context, Appellant respectfully submits that no *prima facie* case of obviousness presently exists with respect to claims 1-47. Moreover, when the claimed invention is viewed as a whole, it provides distinct clinical advantages over the combination of Thompson et al. and Goedeke. Accordingly, Appellant respectfully requests reversal of the rejection of claims 1-19 and 28-36.

8. Summary

In summary, because Thompson et al. fails to disclose a wired data transmission between the implantable medical device and the implantable user-attachable or detachable telemetry module, it cannot anticipate any of the present claims 1-47. Moreover, because Thompson et al. and Goedeke fail to disclose, teach, or suggest wired data communication between an implantable medical device and an implantable user-attachable or detachable telemetry module, there is no *prima facie* case of obviousness of claims 1-47, particularly since wired and wireless communication cannot be viewed as functional equivalents in the implantable context, and because the claimed invention as a whole provides practical clinical and other advantages that are not disclosed, taught, or suggested by Thompson et al. and Goedeke.

Therefore, Appellant respectfully requests reversal of all bases of rejection of all claims.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application and to avoid an appeal.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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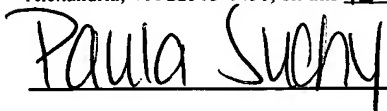
Date December 16, 2005

By 

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